
Citation:

Farrin, A and Hartley, S and Graham, L and Kelley, R and Surr, C and Griffiths, A and Bryant, L (2015) Conducting complex intervention trials in populations at risk of diminished capacity. In: 3rd International Clinical Trials Methodology Conference.

Link to Leeds Beckett Repository record:

<https://eprints.leedsbeckett.ac.uk/id/eprint/4199/>

Document Version:

Conference or Workshop Item (Published Version)

Creative Commons: Attribution 4.0

The aim of the Leeds Beckett Repository is to provide open access to our research, as required by funder policies and permitted by publishers and copyright law.

The Leeds Beckett repository holds a wide range of publications, each of which has been checked for copyright and the relevant embargo period has been applied by the Research Services team.

We operate on a standard take-down policy. If you are the author or publisher of an output and you would like it removed from the repository, please [contact us](#) and we will investigate on a case-by-case basis.

Each thesis in the repository has been cleared where necessary by the author for third party copyright. If you would like a thesis to be removed from the repository or believe there is an issue with copyright, please contact us on openaccess@leedsbeckett.ac.uk and we will investigate on a case-by-case basis.



Recruitment, consent and data collection in research involving care home residents with dementia – lessons from the EPIC trial

Prof Claire Surr
EPIC Chief Investigator
Leeds Beckett University



The Telegraph

WINNER

Research Team of the Year

Institute of
Psychiatry
at The Maudsley



Oxford Health **NHS**
NHS Foundation Trust



UNIVERSITY of
BRADFORD

Bradford District
Care Trust



Newcastle
University



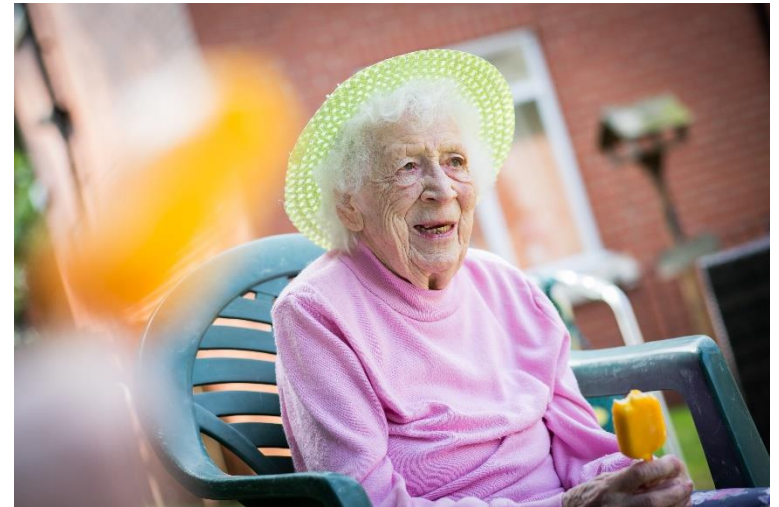
Background

- Over 16,000 care homes (nursing and residential) in England (CQC 2016)
- Resident population of over 460,000 (CQC 2016)
- One-third of people with dementia live in a care home (Knapp et al 2007)
- Estimated that c.70% of care home residents have dementia (Alzheimer's Society 2016)
- Issues with care quality and meeting of resident needs



Conducting trials in care homes

- Significant need for research in this setting
- Comparatively few RCTs conducted in care homes
- Care homes therefore not 'research ready'
- Poor understanding of research and its processes and procedures
- Many see value in being research active



EPIC trial (Surr et al 2016) recruitment of care home residents with dementia to research

- Follows standard process for assessment of capacity
 - Individual informed consent OR appointment of personal or nominated consultee
- 145/726 (20.0%) personal consent
- 263/726 (36.2%) personal consultee
- 318/726 (43.8%) nominated consultee

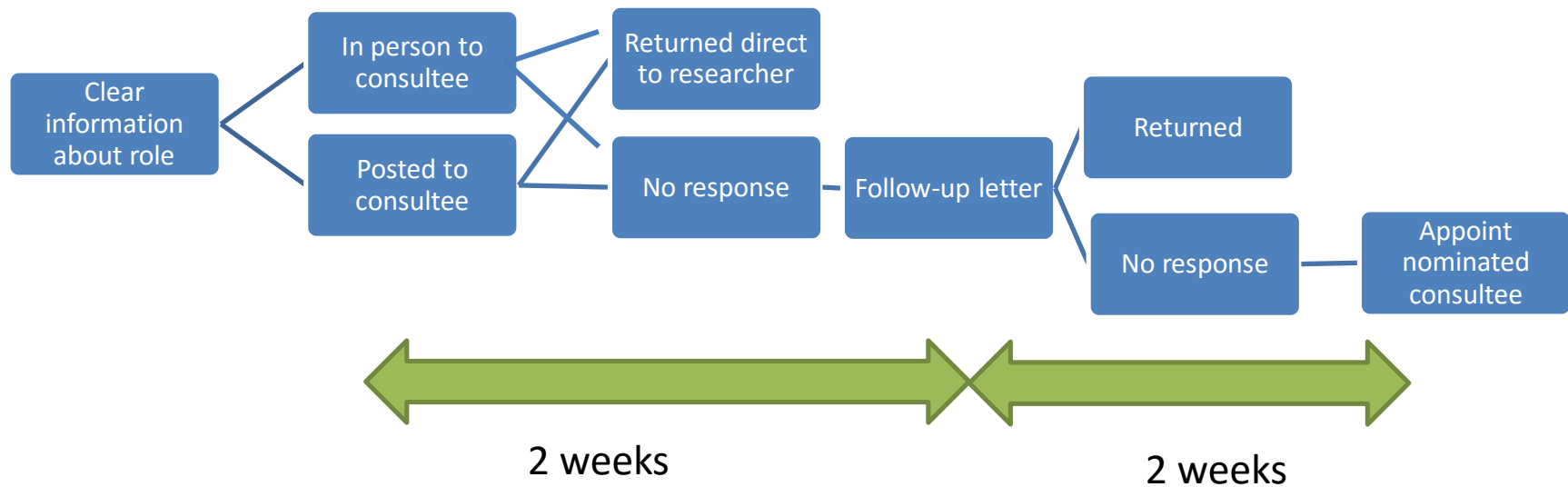


EPIC trial challenges - approaching personal consultees



- Access to personal details – data protection
- May not visit frequently/live at a distance
- May not respond to correspondence
- Can be left with ‘unknown’ status of invited participants
- Personal views rather than participant’s wishes

EPIC trial solutions – personal consultees



EPIC trial challenges - approaching nominated consultees

- Finding suitable individual
- Concerns about role and providing advice on residents wishes
- Concerns about family views if personal consultee did not respond
- Staff turnover and finding replacement consultee



EPIC trial solutions – nominated consultees



- Where possible one consultee for multiple residents
- Spend time explaining role and discussing concerns
- Emphasise right of residents to take part in research if they would wish to – not be excluded due to non-response of family
- Emphasise ability to withdraw later if relatives make contact and advise differently

Resident outcomes QoL - challenges

- Consistent person to report/complete measure (self vs proxy)
- Discrepancy between self vs proxy reports (Arons et al 2013; Buckley et al 2012)
- Sensitivity in moderate/severe dementia
- Residents
 - Suitable measure for moderate to severe dementia
 - Items relevant to care home residents
 - Burden/time
 - Enjoyable and not cause distress
- Staff
 - Turnover and availability
- Relatives
 - Engagement
 - Frequency of visiting



Resident outcomes - solutions



- DEMQOL
 - MMSE 10+
 - 28 items
- QOL-AD
 - MMSE 3+
 - 13 items

But QOL-AD

Instructions: Interviewer administers according to standard instructions. Circle participant responses.

| | | | | |
|--|------|------|------|-----------|
| 1. Physical health | Poor | Fair | Good | Excellent |
| 2. Energy | Poor | Fair | Good | Excellent |
| 3. Mood | Poor | Fair | Good | Excellent |
| 4. Living situation | Poor | Fair | Good | Excellent |
| 5. Memory | Poor | Fair | Good | Excellent |
| 6. Family | Poor | Fair | Good | Excellent |
| 7. Marriage | Poor | Fair | Good | Excellent |
| 8. Friends | Poor | Fair | Good | Excellent |
| 9. Self as a whole | Poor | Fair | Good | Excellent |
| 10. Ability to do chores around the house | Poor | Fair | Good | Excellent |
| 11. Ability to do things for fun | Poor | Fair | Good | Excellent |
| 12. Money | Poor | Fair | Good | Excellent |
| 13. Life as a whole | Poor | Fair | Good | Excellent |

The QOL-AD (Participant Version) from
Logsdon et al (2002)

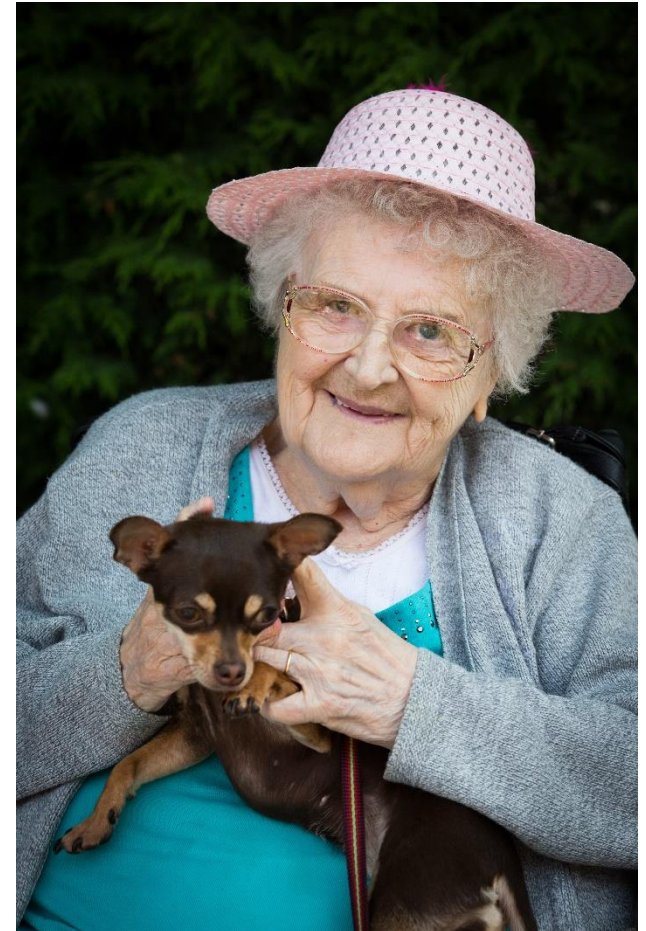
QOL-AD-res (Edelman et al 2005)

Removes two items and adds four new ones:

- people who work here,
- ability to take care of oneself,
- ability to live with others, and
- ability to make choices in one's life

Summary

- Conducting trials in care homes with people with dementia can be challenging
- Lack of/no consistent, direct access to relatives
- CH staff not used to research roles and processes
- Lack of suitable measures for use in this population
- Be pragmatic and do things differently/push boundaries



EPIC trial team

Co-applicants: Claire Surr¹, Clive Ballard², Lynn Chenoweth³, Anne Corbett¹¹, Murna Downs⁴, Amanda Farrin⁵, Jane Fossey⁶, Liz Graham¹³, David Meads⁵, Louise Robinson⁷, Najma Siddiqi⁸, Graham Stokes⁹, Rebecca Walwyn⁵.

Team members: Chris Albertyn², Natasha Burnley¹, Elyse Couch², Byron Creese¹¹, Sue Fortescue¹⁰, Lucy Garrod⁶, Madeline Goodwin⁵, Alys Griffiths¹, Ivana Holloway⁵, Sharon Jones⁴, Joanne McDermid², Vicki McLellan⁵, Holly Millard⁶, Devon Perfect⁶, Olivia Robinson¹, Emily Shoesmith¹, Victoria Simons⁶, Emily Standell⁶, Laura Stubbs⁵, Miguel Vasconcelos Da Silva², Daphne Wallace⁴, Juni West¹², and Ian Wheeler⁵.

¹Leeds Beckett University, ²Kings College London, ³University of New South Wales, ⁴University of Bradford, ⁵University of Leeds, ⁶Oxford Health NHS Foundation Trust, ⁷Newcastle University, ⁸Bradford District Care Trust, ⁹Bupa, ¹⁰Alzheimer's Society Research Volunteer Network, ¹¹University of Exeter, ¹²Norfolk and Suffolk NHS Foundation Trust, ¹³Bradford Institute for Health Research.

Funder statement

This project was funded by the National Institute for Health Research Health Technology Assessment Programme (project number 11/13/15)
The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the HTA NIHR, NHS or the Department of Health.

Contact

epic@leedsbeckett.ac.uk or c.a.surr@leedsbeckett.ac.uk

Website: <http://www.leedsbeckett.ac.uk/pages/epic-trial/>

Twitter: @epictrial

References

- Alzheimer's Society (2016) *Fix dementia care: NHS and care homes*. London: Alzheimer's Society
- Arons, A.M.M., Crabbe, P.F.M., Schölzel-Dorenbos, C.J.M., van der Wilt, G.J. and Olde Rikkert, M.G.M. (2013) Quality of life in dementia: a study on proxy bias *BMC Medical Research Methodology* 13: 110
- Buckley, T. et al (2012) Predictors of Quality of Life Ratings for Persons with Dementia Simultaneously Reported by Patients and their Caregivers: The Cache County (Utah) Study. *International Psychogeriatrics*. 24(7): 1094-1102
- CQC (2016) *The state of health care and adult social care in England 2015/16* London: CQC
- Edelman P, Fulton BR, Kuhn D, Chang CH. (2005) A comparison of three methods of measuring dementia-specific quality of life: Perspectives of residents, staff, and observers, *The Gerontologist* 4:27-36
- Knapp M, Prince M, Albanese E, Banerjee S, Dhanasiri S, Fernandez JL et al. (2007) *Dementia UK: Report to the Alzheimer's Society*. London: Alzheimer's Society.
- Logsdon, R et al (2002) Assessing Quality of Life in Older Adults With Cognitive Impairment *Psychosomatic Medicine* 64: 510-519
- Surr, C.**, Walwyn, R., Lilley-Kelley, A., Cicero, R., Meads, D., Ballard, C., Burton, K., Chenoweth, L., Corbett, A., Creese, B., Downs, M., Farrin, A.J., Fossey, J., Garrod, L., Graham, E.H., Griffiths, A., Holloway, I., Jones, S., Malik, B., Siddiqi, N., Robinson, L. and Wallace, D. (2016) Evaluating the effectiveness and cost effectiveness of Dementia Care Mapping™ to enable person-centred care for people with dementia and their carers (DCM-EPIC) in care homes: Study protocol for a randomised controlled trial. *Trials*. 17:300. DOI: 10.1186/s13063-016-1416-z